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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,909	01/10/2006	Marco Pirovano	4017-41	5626

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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
MEHTA, BHISMA	
ART UNIT	PAPER NUMBER
3767	
MAIL DATE	DELIVERY MODE
09/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,909	PIROVANO ET AL.	
	Examiner	Art Unit	
	BHISMA MEHTA	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *75-92* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *75-92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 27, 2009 has been entered.

Claim Objections

2. Claims 75-92 are objected to because of the following informalities: Claim 75 recites the limitations "said pharmacological solution" in lines 4-6 and "said flow in lines 6, 7, and 9. Claim 81 recites the limitation "said pharmacological solution" in line 3. Claim 82 recites the limitation "said pharmacological solution" in line 3. There is insufficient antecedent basis for these limitations in these claims. It should be noted that the pharmacological solution has not been positively recited in line 3 of claim 75. If Applicant intends to positively claim the pharmacological solution, it is suggested that the pharmacological solution be positively recited. If Applicant does not intend to positively claim the pharmacological solution, it is suggested that "said pharmacological solution" be replaced with "the pharmacological solution". Similarly, the flow of the pharmacological solution has not been positively recited. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 75-92 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 75-92 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The infusion protocol according to which the pulsed actuation is made where the infusion protocol comprises a pre-programmed series of openings and closings of the valve arrangement with preset durations and at preset intervals of time is not disclosed in the specification as originally filed. It appears that the disclosure of the series of openings and closings of the valve arrangement with preset durations and at preset intervals of time relates to the calibration of the valve or the valve arrangement and is not related to the infusion protocol (see paragraph [0051]). There is no disclosure in the specification as originally filed that the infusion protocol is related to the series of openings and closings of the valve arrangement with preset durations and at

preset intervals of time. Furthermore, the infusion protocol appears to be related to the type of pharmacological solution to be used and the maximum volume of pharmacological solution to be delivered (see paragraph [0050]).

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 89 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 89, it is unclear if the battery is being claimed as being an electrical supply to the command and control device or if the battery is being claimed as the command and control device.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 75-79, 81, 82, and 89-92 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin (U.S. Patent No. 4,976,687). In lines 4-24 of column 3 and in lines 4-68 of column 6, Martin discloses an infusion system having an elastomeric container (30) for containing a pharmacological solution and for generating a flow of the solution from the container to a catheter (17, 112) where the elastomeric container, in use, is configured to exert a pressure on the pharmacological solution (lines 13-23 of column

6), a valve arrangement (14, 110) to vary the flow, and a command and control device (116). The command and control device is operationally connected to the valve arrangement to command a pulsed actuation of the valve arrangement where the flow is determined by the number of actuations of the valve arrangement per unit time (lines 55-68 of column 6). Martin discloses an infusion protocol according to which the pulsed actuation is made where the infusion protocol comprises a pre-programmed series of openings and closings of the valve arrangement with preset durations and at preset intervals of time (lines 55-68 of column 6). As to claim 76, see lines 55-68 of column 6. As to claim 77, see lines 24-30 of column 6. As to claim 78, the command and control device comprises a microprocessor. As to claim 79, the elastomeric container is supported on a support element (10) associated with a containing and protection element (28) (lines 36-45 of column 3). As to claims 81 and 82, the containing and protection element comprises an inlet portion (36, 107) connected to the elastomeric container where the inlet portion is associated with an introducing device (34, 104). As to claims 89 and 90, the system has a battery (102) which is rechargeable or replaceable. As to claim 91, see lines 31-68 of column 6. As to claim 92, the elastomeric container is structured or configured to exert a pressure on the pharmacological solution as disclosed in lines 13-23 of column 6.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 80 and 83-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Kanai et al (U.S. Patent No. 6,367,502). Martin discloses the system substantially as claimed. Even though Martin discloses a containing and protection element, Martin is silent on the containing and protection element being made of transparent material and being equipped on its outside surface with a graduated scale. Also, even though Martin discloses an inlet portion, Martin is silent on the containing and protection element having both an inlet and an outlet portion. Kanai et al disclose an infusion system having a pumping device comprising an elastomeric container (11) which is supported on a support element (10) associated with a transparent containing and protection element (2). The containing and protection element has a graduated scale (4). The containing and protection element has an inlet portion (19) with a check valve (13) and a connecting element (17) and an outlet portion (18) which is connected to a first end of a fitting element (30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the containing and protection element of Martin from a transparent material and with a graduated scale as taught by Kanai et al as both Martin and Kanai et al disclose infusion systems having an elastomeric container and a containing and protection element and Kanai et al disclose that it is well known to make the containing and protection element from a transparent material and having a scale to allow one to determine the amount of solution within the system. It also would have been obvious to

one having ordinary skill in the art at the time the invention was made to provide the containing and protection of Martin with an outlet portion as taught by Kanai et al as Kanai et al disclose providing the containing and protection element with an inlet portion and an outlet portion in order to both deliver a flow of solution to the patient through one portion and to allow for injecting the solution through the other portion. As to claim 85, Martin discloses a connecting element (36) associated with the valve arrangement and suitable for enabling coupling of the valve arrangement with a delivery device.

11. Claims 86-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Franetzki et al (U.S. Patent No. 4,270,532). Martin discloses the system substantially as claimed. Even though Martin discloses a command and control device, Corbin et al are silent on the specifics of an interface element for operationally connecting the command and control device with a data processing system and a reading device. Franetzki et al disclose an infusion system having a container and a command and control device comprising a microprocessor (I). The command and control device also has an interface element for operationally connecting the command and control device to a data processing system (44) and a reading device for receiving a data recording support in the form of a smart-card type (lines 38-52 of column 2 and lines 3-24 of column 7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the command and control device of Martin with an interface element as taught by Franetzki et al as Franetzki et al disclose that it is well known to use a command and control device having an interface element to allow the desired infusion to be pre-programmed and monitored by a physician. To

provide the command and control device of Martin with a reading device as taught by Franetzki et al would have also been obvious to one having ordinary skill in the art at the time the invention was made as Franetzki et al disclose that it is well known to use a command and control device having a reading device to allow for the programming data which is already stored on a carrier or card to be easily read by the command and control device.

Response to Arguments

12. Applicant's arguments with respect to claims 75-92 have been considered but are moot in view of the new ground(s) of rejection. As to Applicant's arguments in lines 10-14 of page 8, Martin discloses an elastomeric container which is capable of exerting a pressure on the pharmacological solution as claimed (see lines 13-23 of column 6). Furthermore, in response to applicant's argument that there is no explicit disclosure that the elastomeric container of Martin exerts a pressure on the pharmacological solution, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-

3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767